



# NASA Procedural Requirements

**COMPLIANCE IS MANDATORY**

**NPR 7100.1**

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2003

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2008

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## Subject: Protection of Human Research Subjects

**Responsible Office: Office of the Chief Health & Medical Officer**

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## CHAPTER 9. Criteria for IRB Approval of Research Involving Human Subjects

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9.1 The following requirements must be satisfied for the IRB to approve the research involving human subjects covered by this NPR:

9.1.1 The PI shall always protect the safety and minimize health risk to subjects: (1) by selecting methodologies and procedures which are consistent with sound research design and conduct and which do not unnecessarily expose subjects to undue risk; and (2) whenever possible, by using procedures already being performed on the subjects for other experiments, so as to minimize the collective impact of multiple protocols on the subject.

9.1.2 In evaluating safety risks and benefits, the IRB shall ensure that risk to subjects be reasonable in relation to anticipated benefits, if any, and the importance of the new knowledge that may reasonably be expected to result. The IRB should consider only those risks and benefits, taking into account the collective impact of multiple protocols that may result from the research. The IRB should not consider possible long-range effects of new knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks or benefits that are its responsibility.

9.1.3 The PI shall obtain and document the voluntary informed consent of each prospective subject or the subject's legally authorized representative. The human research consent form shall contain at least all elements listed in section 7.2 (and section 7.5, if appropriate). The PI shall inform the subject that not all risks are readily identifiable.

9.1.4 The PI may ensure that the subject or the subject's beneficiaries receive compensation by means of insurance, worker's compensation, or the like in the event that the subject suffers illness, disease, injury, loss, or death as a direct result of the research. The lack of this provision may serve as a basis for disapproval of the research. Such provisions for compensation shall be required for all studies performed at a NASA Center.

9.1.5 Where applicable, the research proposal shall contain provisions for monitoring the data collected to ensure the safety of the subjects. Other informational items that should be included in a human research proposal are listed in Appendix A.

9.1.6 The PI shall provide safeguards to protect the privacy of subjects and the confidentiality of data, especially electronically stored data. Biomedical data, if held by NASA and if retrievable by personal identifier, are subject to the Privacy Act of 1974, as amended, 5 U.S.C. 552a, and are maintained under the NASA System of Records, Human Experimental and Research Data (HERD) Records. Such data held by other institutions must have similar safeguards. The PI shall maintain the records relating to the conducted research and shall retain these records for at least 3 years after completion of the research.

9.1.7 No human subject shall participate in any portion of the research until the protocol is approved by the IRB.

9.1.8 The PI shall ensure that selection of subjects is equitable and representative of the population that its biomedical research intends to represent. The IRB should assess the purposes and setting of the research. In the case of space flight, considerations should be given to the habitability conditions and the level of medical care available in the event of illness or injury.

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